

5-17-93

UNITED STATES OF AMERICA
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF)

ACETO AGRICULTURAL CHEMICALS)

Petitioner)

FIFRA DATA Docket No. 199

ACCELERATED DECISION AND ORDER

WHEREAS, Respondent and Petitioner have reached a settlement in the above-captioned case;

WHEREAS, Respondent and Petitioner have filed a joint motion for ACCELERATED DECISION;

WHEREAS, I find and determine that the SETTLEMENT AGREEMENT signed by the parties represents a fair and reasonable resolution of the issues raised in this case;

NOW, THEREFORE, IT IS ORDERED, ADJUDGED AND DECREED THAT:

1. The Motion for an ACCELERATED DECISION under 40 CFR 164.91(a)(8) is granted.

2. The terms and conditions set out in the SETTLEMENT AGREEMENT between the parties dated May 13, 1993 are hereby approved and incorporated into this Order by reference and made applicable to Respondent and Petitioner.


Daniel M. Head
Administrative Law Judge

Dated:

May 17, 1993
Washington, D.C.

SETTLEMENT AGREEMENT

Aceto Agricultural Chemicals Corporation ("Aceto") and the Environmental Protection Agency ("EPA") have reached the following agreement concerning the generation of product chemistry data to support Aceto's registrations of pesticide products containing chlorpropham as an active ingredient. This agreement resolves the outstanding dispute between Aceto and EPA involved in FIFRA Data Docket No. 199. This written agreement constitutes the entire agreement between Aceto and EPA.

1. Aceto will submit the following guideline studies to the Agency in support of its registered technical product bearing EPA Registration No. 2749-102 according to the following schedule:

GUIDELINES**DUE DATES**

63-8; 63-9; 63-11

May 17, 1993

62-1; 62-2

May 31, 1993

63-20

June 30, 1993

63-17 (90 day report)

June 30, 1993

63-17 (final study)

May 31, 1994

2. All data identified in paragraph 1 shall be delivered by hand on or before the due date to either Venus Eagle, Walt Waldrop, or any other individual identified by EPA if either Ms. Eagle or Mr. Waldrop will not be available on the scheduled due date. Aceto shall telephone Ms. Eagle, Mr. Waldrop, or any replacement individual designated by EPA prior to the delivery in

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(order to finalize the time and date of delivery of any item of data.

3. No extension of any of the due dates identified in paragraph 1 shall be considered granted by EPA unless such extension is granted by EPA in writing.

4. Aceto consents to the suspension of its registered technical product bearing EPA Registration No. 2749-102 to take effect on July 2, 1993.

5. Aceto consents to the immediate suspension of its technical registration for chlorpropham bearing EPA Registration No. 2749-117. This registration shall remain suspended until such time as EPA determines that adequate product chemistry data has been submitted to support that registration or until it is cancelled.

6. EPA will attempt to complete within thirty days of receipt its review of any data identified in paragraph 1 other than the final storage stability data (guideline 63-17), and of any other product chemistry data submitted by Aceto to meet any of the data requirements identified in the Agency's letter of November 12, 1992 (which is incorporated by reference into this Agreement). If such data are submitted prior to the submission of the final storage stability data discussed in paragraph 7, EPA shall complete its review of the data not later than thirty days after submission of the final storage stability data. If EPA

determines that any product chemistry data other than the final storage stability data are deficient, EPA shall notify Aceto in writing of the deficiency and any bases therefor, and allow Aceto 3 business days from the date of receipt of EPA's notification to correct all deficiencies.

7. EPA will complete its review of the final storage stability data (guideline 63-17) within thirty days of receipt, and will notify Aceto in writing within such thirty day period whether the submitted data constitute an adequate response to the data requirement. If the data are determined by EPA to be deficient in any way, EPA will provide Aceto in the written notice of the bases for the determination, and will review any corrections or further submittals by Aceto in accordance with the requirements of this paragraph. If the data are determined to be satisfactory, and if all the other data requirements identified in paragraph 1 have been met to EPA's satisfaction, EPA will terminate any suspension entered pursuant to paragraph 4, 8, or 9 and in the written notice notify Aceto that the suspension has been lifted.

8. If EPA notifies Aceto pursuant to paragraph 6 that any product chemistry data submitted by Aceto between April 1, 1993 and January 1, 1994 are deficient, and all deficiencies are not deemed corrected by EPA within the time period provided in paragraph 6, EPA shall have the right to immediately suspend the registration of every pesticide product containing chlorpropham

registered to Aceto with the exception of the technical product bearing EPA Registration No. 2749-117. Such suspension shall take effect upon written notification to Aceto. The products subject to the terms of this paragraph have the following registration numbers:

2749-70

2749-102

2749-264

9. If Aceto fails to submit by the applicable due date any data required by paragraph 1 to be submitted in 1993, EPA shall have the right to immediately suspend the registration of every pesticide product containing chlorpropham registered to Aceto and identified in paragraph 8. Such suspension shall take effect upon written notification to Aceto.

10. It will be a violation of FIFRA for Aceto to sell or distribute existing stocks of any product suspended pursuant to this agreement during the pendency of any suspension, except that Aceto shall be permitted to sell or distribute until August 1, 1993 stocks of its technical product bearing EPA Registration No. 2749-102 that have entered the United States on or before the date of suspension.

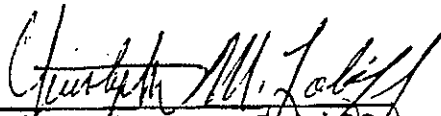
11. Any registration suspended pursuant to this agreement shall remain suspended until all the data requirements identified in EPA's letter of November 12, 1992 have been met to the Agency's

GENERAL COUNSEL 444 M.W. & E D.C. 008

satisfaction: EPA shall terminate any suspension entered pursuant to this Agreement immediately upon final determination by the Agency that all of the identified data requirements have been satisfied, and shall immediately notify Aceto in writing of the lifting of the suspension(s).

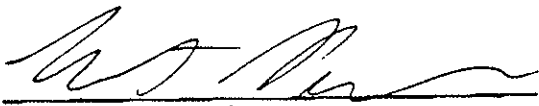
12. Aceto waives any right to challenge any action taken by EPA pursuant to this agreement.

13. EPA agrees not to proceed before May 1, 1995 with any suspension action against any pesticide product not registered to Aceto based upon any failure of Aceto to fulfill the data requirements identified in EPA's letter of November 12, 1992.


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Washington, D.C. 20006-2296

Counsel for Petitioner

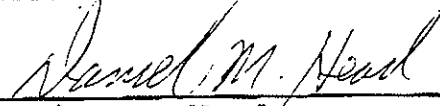
Date: May 13, 1993


Robert Perlis
Office of General Counsel
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Counsel for Respondent

Date: May 13, 1993

BY ORDER ENTERED TODAY I HAVE APPROVED THIS SETTLEMENT AGREEMENT.


Daniel M. Head
Administrative Law Judge

Dated: May 17, 1993

CERTIFICATE OF SERVICE


I do hereby certify that the foregoing Accelerated Decision and Order was filed in re Aceto Agricultural Chemicals Corporation; FIFRA Data Docket 199 and a copy of the same was mailed to the following:

(Inter Office)

Robert Perlis, Esq.
Office of General Counsel
(LE-132P)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

(First Class Mail)

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1850 K Street, NW
Washington, DC 20006-2296



Susan B. Eggen
Office of the Hearing Clerk
U. S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dated: May 17, 1993